II. REMARKS

A. Status of the claims

Claims 8, 20 and 46 have been amended without prejudice.

New claims 50-55 have been added.

Support for the amended and new claims can be found in the original claims and throughout the specification, e.g., in paragraphs [0108] to [0110] of the specification and in original claims 36, 37, 38, and 44.

Claims 8-11, 13, 14, 16, 20, 22-24, 29, 30, 32-38, and 40-55 are pending.

Applicants respectfully submit that no new matter has been added by virtue of this amendment.

B. Rejection under 35 U.S.C. § 103

Claims 8-11, 13, 14, 16, 20-24, 29, 30, 32-38, and 40-49 were rejected under 35 U.S.C. § 103 (a) over U.S. Patent No. 4,910,205 to Kogan et al. in combination with U.S. Patent No. 5,968,547 to Reder et al. The Examiner stated:

> Loratadine was known at the time of invention to be administered transdermally as disclosed by Kogan. Reder taught that when the drug is included in the described transdermal device, the drug follows and is delivered according to its pharmacokinetics for period of 5 days as desired by applicants. Applicants disclosed on the paragraph bridging page 23 and 24 that the pharmacokinetic information for oral loratadine is available in the literature and a release rate for a loratadine transdermal delivery system was calculated from the available data.

Office Action, page 8.

The rejection is respectfully traversed.

Independent claims 8, 20 and 46 recite in part a transdermal delivery system comprising an active agent consisting of loratadine, exhibiting the specific release profile (specific release rates at 24 hours, 48, hours, 72 hours, and 96 hours) and maintaining a therapeutic blood level of loratadine until the end of at least the five-day dosing interval.

The Examiner has relied on the Reder patent for the teaching of a transdermal delivery system that releases the drug over a period of five days. *Office Acton, page 8.*

The Reder patent is directed to methods of providing sustained analgesia with active agents described therein. The Reder patent does not teach or suggest a transdermal delivery system containing loratadine.

Applicants note that in the submission dated December 21, 2006, on page 11 and 12, Applicants stated that "the subject matter of the Reder patent is limited to transdermal delivery devices of buprenorphine for the treatment of pain or opioid addiction," and that "a formulation prepared in accordance with teachings of the Reder reference must contain buprenorphine." (emphasis in the original). Having reviewed the Reder patent again, Applicants note that the teaching of the Reder patent are not limited to buprenorphine, but also extends to other active agents (i.e., opioids). *See column 17, lines 51, to column 18, line 6.* Applicants submit that the physical, chemical and pharmacological properties of the active agents of the Reder patent are different from the physical, chemical and pharmacological properties of loratadine. It is further submitted that given the vast differences between the active agents described in the Reder patent and loratadine, the teaching of the Reder patent (i.e., relative mean release rates) do not extend to loratadine.

Accordingly, it is respectfully submitted that there is no suggestion in the Reder patent of the desirability of the claimed specific release rates of loratadine, let alone the

specific claimed release profile of loratadine (specific release rates at 24 hours, 48, hours, 72 hours, and 96 hours).

The Kogan patent also lacks a suggestion of the specific claimed release profile of loratadine. In fact, the Examiner has acknowledged that the Kogan patent "does not teach the specific delivery profile of loratadine." *Office Action, page 4.*

It is respectfully submitted that in order for someone to alter the loratadine formulation of the Kogan patent, someone would have to decide that loratadine release rate of the Kogan patent is problematic; and that loratadine can be administered in a transdermal delivery system that maintains a therapeutic blood level of loratadine until the end of at least the five-day dosing interval as recited in the present claims. Then, that person would have to decide on how to determine the amounts that will be included in the transdermal delivery system and a particular manner of accomplishing this task.

There is no information provided in the cited references that speaks of the unacceptability of the Kogan release rate or suggests that a transdermal delivery system that maintains a therapeutic blood level of loratadine as recited in the present claims would be efficacious or beneficial.

Nevertheless, the Examiner purportedly suggested that it is completely permissible to alter the Kogan formulation to an entirely different formulation (i.e., the buprenorphine formulation of Reder), and then, based, purely on the knowledge learned from the present specification, asserted that it would have been obvious to arrive at the release rates via a connection made only in the present specification.

It is respectfully submitted that the present specification is not part on the prior art and it is impermissible for the Examiner to rely on the knowledge learned from the present specification to support an obviousness rejection. In fact, none of the exemplary rationals for supporting a conclusion of obviousness provide for the use of the specification as a "road map" to obviousness. *See MPEP, section 2143.*

For the foregoing reasons, withdrawal of the rejection is respectfully requested.

With further regard to new claims 53 to 55, it is respectfully submitted that the combination of the cited references does not teach or suggest a transdermal delivery system comprising "a solution of an active agent consisting of loratadine," as none of the cited references describe a solution of loratadine.

The Kogan patent teaches measuring flux rates with a Franz diffusion cell. *Column 3, lines 28-30.* It is respectfully submitted that the Franz diffusion cell test is "**not** suitable for evaluation of solution or suspension-formulations … due to its inherent upright, open donor compartments design, which does not permit the use of any stirring setup as in the receptor compartment." *Development of a Dynamic Skin Permeation System for Long-Term Permeation Studies*, Drug development and Industrial Pharmacy, 10(4), page 577 (1984), attached as part of Appendix A.

Accordingly, it is respectfully submitted that the Kogan patent does not teach or suggest a transdermal delivery system comprising a solution of loratadine.

The Reder patent also does not teach a transdermal delivery system comprising a solution of loratadine, as there is no mention of loratadine in the Reder patent.

Accordingly, the combination of the cited references would not have suggested to one skilled in the art a transdermal delivery system comprising a solution of loratadine as recited in new claims 53-55.

III. CONCLUSION

An early and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned by telephone if a telephone interview would advance prosecution of the present application.

Respectfully submitted,
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